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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/470,276	12/22/1999	RICHARD KOLODNER	157/47483-C	5964

7590 05/31/2002

NIXON PEABODY LLP
101 FEDERAL ST
BOSTON, MA 02115

EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 05/31/2002

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/470,276

Applicant(s)

KOLODNER ET AL.

Examiner

FREDMAN

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-8, 10, 12 and 39-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3, 5-8, 10, 41 and 46-49 is/are rejected.
- 7) ☒ Claim(s) 2, 4, 12, 39, 40 and 42-45 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

General

1. Claim 3 utilizes the transitional term "containing". Because this term lacks any particular meaning in the patent literature, the examiner will interpret "containing" as being equivalent in scope to the open term "comprising".

Claim Rejections - 35 USC § 112

2. The rejection of claims 3, 6-8, 10, 12, 41 and 44 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification is withdrawn in view of the amendment.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 3, 5, 6, 8, 9, 41, 48 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Lage et al (Gene (1996) 178:187-189).

Lage teaches a cDNA sequence which is an isolated nucleotide segment of less than 3000 nucleotides that contains a fragment of 17 contiguous nucleotides from the coding region of SEQ ID NO: 1 as shown in the alignment below.

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Score = 34.2 bits (17), Expect = 0.29
Identities = 17/17 (100%)
Strand = Plus / Plus

Query: 1 gaggaggaggagctggc 17
 |||||
Sbjct: 684 gaggaggaggagctggc 700

Lage further teaches that the isolated nucleic acid was in a vector in a host cell, specifically a lambda cDNA library (page 187, column 1).

5. Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Promega catalog (1993/94) p. 166.

The Promega catalog teaches a kit with a set of DNA primers which permit synthesis of the coding sequence of hMSH5, specifically the random hexameric primers (p. 166).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor

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and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lage et al as applied to claims 3 and 6 in view of Vanin et al (U.S. Patent 5,710,037).

Lage teaches a cDNA sequence which is an isolated nucleotide segment of less than 3000 nucleotides that contains a fragment of 17 contiguous nucleotides from the coding region of SEQ ID NO: 1 as shown in the alignment below.

Score = 34.2 bits (17), Expect = 0.29
Identities = 17/17 (100%)
Strand = Plus / Plus

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Query: 1   gaggaggaggagctggc 17
          |||
Sbjct: 684 gaggaggaggagctggc 700
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Lage further teaches that the isolated nucleic acid was in a vector in a host cell, specifically a lambda cDNA library (page 187, column 1).

Lage does not teach placement of the sequence into a retroviral vector.

Vanin teaches placement of genes of interest into retroviral vectors (column 3, lines 18-45).

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It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to utilize the retroviral vector of Vanin to express the synthetase gene of Lage since Vanin states "Attractive features of retroviral vectors include flexibility, that is the variety of coding sequences that can be transferred, high although variable transduction efficiency, and stability of the proviral genome once integrated into a host cell chromosome (column 1, lines 21-24)". An ordinary practitioner would have been motivated to clone the gene of Lage into a retroviral vector as taught by Vanin since the vector is flexible, stable and has high transduction efficiency.

8. Claims 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lage et al as applied to claims 3 and 41 in view of Dattagupta et al (EP 297,379).

Lage teaches a cDNA sequence which is an isolated nucleotide segment of less than 3000 nucleotides that contains a fragment of 17 contiguous nucleotides from the coding region of SEQ ID NO: 1 as shown in the alignment below.

Score = 34.2 bits (17), Expect = 0.29
Identities = 17/17 (100%)
Strand = Plus / Plus

Query: 1 gaggaggaggagctggc 17
 |||||
Sbjct: 684 gaggaggaggagctggc 700

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Lage further teaches that the isolated nucleic acid was in a vector in a host cell, specifically a lambda cDNA library (page 187, column 1).

Lage does not teach labeling the nucleic acid.

Dattagupta teaches the use of fluorescence labels (column 9, lines 25-31).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the nucleic acid of Lage with the fluorescent labels of Dattagupta since Dattagupta states "the incorporation of labels will be the direct indication of the specific processes and hence the presence of a specific test sequence (column 9, lines 27-30)". An ordinary practitioner would have been motivated to use the fluorescent labels of Dattagupta with the nucleic acid of Lage for the stated benefit of identifying a specific target sequence and the expected benefits of sensitivity and specificity known in the art to result from fluorescent labels.

Allowable Subject Matter

9. Claims 2, 4, 12, 39, 40, 42, 43, 44 and 45 are allowed.
10. The following is a statement of reasons for the indication of allowable subject matter: The claimed sequences are novel and unobvious over the cited prior art.

Response to Arguments

11. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

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Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman, Ph.D. whose telephone number is (703) 308-6568.

The examiner is normally in the office between the hours of 6:30 a.m. and 4:00 p.m., and telephone calls either in the morning are most likely to find the examiner in the office.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).



Jeffrey Fredman
Primary Patent Examiner
Art Unit 1637

May 24, 2002